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510(k) Summary

Date Prepared: May 5, 2011

1. **Owner's Name:** **PruGen, IP Holdings Inc.**
8714 E. Vista Bonita Drive
Scottsdale, AZ 85255

Contact Person: **Robert L. Knechtel, M.D., J.D.**
(T): 480-563-2406
(F): 815-261-5953
(E): rknechtel@prugen.com

2. **Proprietary Name:** Emulsion SB™
Common Name: Topical Emulsion for skin
Classification Name: Dressing, Wound & Burn, Hydrogel w/ Drug or Biologic (Product Code FRO)

3. **Substantially Equivalent Device:**

PruGen IP Holdings, Inc. believes that Emulsion SB™ is substantially equivalent to the following currently marketed device: Epiceram® cleared under K052643.

4. **Device Description:**

Emulsion SB™ is a non-sterile, viscous, lipid rich emulsion intended for topical application. It is presented for prescription (requiring a physician diagnosis disease state) use in a 90 gm tube.

5. **Intended Use of the Device:**

Emulsion SB™ is intended to be used as a topical skin care preparation applied at least twice daily to affected areas of the skin to improve dry skin conditions and to relieve and to manage the burning and itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment.

6. **Summary of Technical Characteristics of Device compared to Predicate Devices**

The referenced predicate device is a non-sterile emulsion that is applied topically to relieve the symptoms of various dermatoses, including, but not limited to atopic dermatitis, irritant contact dermatitis, and radiation dermatitis.

7. **Testing and Conclusions:**

Functional and performance testing has been conducted to assess the safety and efficacy of Emulsion SB™ and the results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PruGen IP Holdings, Inc.
% Robert L. Knechtel, M.D., J.D.
SVP and General Counsel
8714 E. Vita Bonita Drive
Scottsdale, Arizona 85255

JUN - 3 2011

Re: K110732
Trade/Device Name: Emulsion SB™
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 23, 2011
Received: March 16, 2011

Dear Dr. Knechtel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

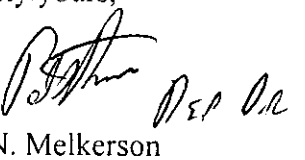
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Date: May 5, 2011

Original: February 23, 2011

INDICATIONS FOR USE

Device Trade Name: Emulsion SB™

510(k) number: K110732

Rx Only

FOR TOPICAL DERMATOLOGICAL USE ONLY

Emulsion SB™ is to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, and radiation dermatitis. Emulsion SB™ helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Prescription Use X
(21 CFR 801 Subpart D)

Over-The-Counter _____
(21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110732